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EXAMINER	
BLAND, LAYLA D	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,455	PERPLIES ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-9 and 11-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-9 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 15, 2007 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed September 15, 2007, and amendment and response to the Final Office Action (mailed May 22, 2008), filed September 15, 2007 wherein claim 1 is amended, claim 5 is canceled, and claims 13-15 are newly submitted.

Applicant's remarks submitted September 15, 2008 indicate that claims 1, 3-9, 11, 12, and new claims 13-15 are pending. However, claim 5 is cancelled in to the claim set submitted September 15, 2008. Claims 1, 3, 4, 6-9, and 11-15 are pending and are examined on the merits herein.

In view of the cancellation of claim 5, all rejections made with respect to that claim in the previous office action are withdrawn.

In view of Applicant's amendment submitted September 15, 2008, the rejection of claims 1, 3-9, 11, and 12 under 35 USC 112, second paragraph, with respect to "solvation delay" is withdrawn.

The rejection of claims 1, 3-9, 11, and 12 under 35 U.S.C. 103(a) as being unpatentable over Meukart et al. in view of Herron et al. is withdrawn in view of the new prior art rejection below.

The following are new rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-9, and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood,

107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP states that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The claims herein are drawn to the use of chemical compounds "containing at least one aldehyde group and at least one acid group." Preference is given to compounds of the formula **HOC-[X]$_y$-COOH** as given on page 4 of the specification and in claim 3. Only glyoxylic acid is exemplified.

The specification as originally filed does not provide adequate support for the generic claims herein. The specification merely exemplifies glyoxylic acid. Compounds containing at least one aldehyde group and at least one acid group are limitless and open to any other functionality, and the vast majority of such compounds are not described in the specification. The skilled artisan would also understand that, within that large number of combinations, are a large number of embodiments of immense strructural variation that would not be suitable for crosslinking cellulose ethers, given the fact that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physical and chemical effects and functions.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1, 6-9, and 11-15 are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any compounds containing at least one aldehyde and one acid group. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of glyoxylic acid and the compounds represented by HOC-$[X]_y$-COOH as given on page 4 of the specification and in claim 3, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)

(affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 1, 3, 4, 6-9, and 11-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of reversibly crosslinked cellulose ethers having solvation delay of up to five minutes, does not reasonably provide enablement for reversibly crosslinked cellulose ethers having solvation delay of a plurality of hours. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention.

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method for producing reversibly crosslinked cellulose ethers having solvation delay from a few seconds up to a plurality of hours, prepared using a crosslinking agent in an amount from 0.01 to 0.1 mole per mole of cellulose ether. Thus, the claims taken together with the specification imply that, by reacting the recited amount of crosslinking agent with a cellulose ether, crosslinked cellulose ethers having solvation delay from a few seconds up to a plurality of hours can be obtained.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Menkart et al. (US 3,072,635, January 8, 1963, of record) teaches that, when using dialdehydes to crosslink cellulose ethers, small amounts of aldehyde treating agent should be used, from about 0.005 to 5 weight percent based on the weight of the cellulose derivative. The amount of aldehyde should not be so great that cross-linkages are formed to such an extent that the solubility of the cellulose derivative is materially

impaired [column 4, line 66 – column 5, line 8]. The crosslinked products of Menkart's examples dissolved in water within a few minutes [column 5, Example 1]. Thus, the skilled artisan could conclude that the use of large amounts of crosslinking agent leads to products for which solubility is impaired, and that the use of crosslinking agents in the amounts taught by Menkart leads to products which dissolve within a few minutes.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for products having a solvation delay of up to 5 minutes. However, the specification does not provide working examples or guidance for products having a solvation delay of a plurality of hours. Based on the teachings of Menkart et al., the skilled artisan would have reason to doubt whether a product having solvation delay of a plurality of hours could be prepared using only 0.1 to 0.1 molar equivalents of crosslinking agent.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the teachings of Menkart et al. and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-9, and 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 (and dependent claims) recites the limitation "chemical compounds containing at least one aldehyde group and at least one acid group." Compounds containing at least one aldehyde group and at least one acid group are limitless and open to any other functionality, and the vast majority of such compounds are not described in the specification. The claim is indefinite because the description of said chemical compounds is incomplete and open-ended. The skilled artisan would not be apprised of which compounds are encompassed by the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 6-9, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menkart et al. (US 3,072,635, January 8, 1963, of record) in view of Block (US 4,366,070, December 28, 1982, of record).

Menkart et al. teach a method for producing cellulose derivatives with improved water solubility, comprising treating a cellulose ether with glyoxal [column 1, lines 37-49]. Cellulose ethers such as methyl hydroxyethyl cellulose, ethyl hydroxyethyl cellulose, and others may be used [column 2, lines 10-30]. Particles of the usual range and size of commercial products, between 20 and 350 mesh, are preferred [column 3, lines 1-3]. The glyoxal can be dissolved in a solvent such as acetone, methanol, or water, the cellulose derivative suspended therein with agitation for less than 30 minutes, followed by separation of the liquid to give a solid containing about 20 to 80 percent of an adsorbed solution, followed by oven drying about 100°C, during which the reaction takes place [column 3, lines 14-47]. Another method involves spraying the crosslinking agent onto a mass of particles of moist carboxymethylcellulose which is being subjected to a mixing action [column 3, lines 49-55]. In one example, the reaction takes place over about 30 minutes [column 5, Example 1]. Glyoxal can be used in an amount of 0.001 to 0.2 moles per mole of cellulose derivative [claim 1] or about 0.02-0.5 weight percent [column 5, line 32]. The use of large amounts of crosslinking agent is to be avoided, because it leads to impaired solubility [column 5, lines 3-8]. The products of this method disperse in cold water without forming lumps and dissolve within 15 to 20 minutes [column 3, lines 43-48]. In one example, the product was pulverized after drying [column 6, Example 4]. Although Menkart et al. do not address the reversibility of the reaction, the skilled artisan would understand that the reaction of an alcohol and an aldehyde to form a hemiacetal is a reversible one.

Menkart et al. do not teach a reaction with a chemical compound having at least one acid group and at least one aldehyde group, or glyoxylic acid in particular. Menkart does not teach comminuting and milling before reaction.

Block teaches a cross-linked hydroxyalkyl cellulose reaction product for use in aqueous systems [see abstract]. The product is formed by contacting a hydroxyalkyl cellulose with a cross-linking agent which can be glyoxylic acid or glyoxal [column 5, lines 6-35], and can be carried out an ambient temperatures or from about 50°C to 100°C [column 5, lines 63-68]. The crosslinked products are used in aqueous systems [column 10, lines 9-12].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute glyoxylic acid for glyoxal in the method of Menkart et al. The Supreme Court in KSR reaffirmed the familiar framework for determining obviousness as set forth in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966)), but stated that the Federal Circuit had erred by applying the teaching-suggestion-motivation (TSM) test in an overly rigid and formalistic way. KSR, 82 USPQ2d 1385. Exemplary rationales that may support a conclusion of obviousness include:

- Combining prior art elements according to known methods to yield predictable results;
- Simple substitution of one known element for another to obtain predictable results;
- Use of known technique to improve similar devices (methods, or products) in the same way;
  Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.

- Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

The instant case could be considered either simple substitution of one known element for another or "obvious to try." Menkart teaches a method which differs from the claimed method by the substitution of glyoxylic acid for glyoxal. Glyoxylic acid is known in the art for crosslinking cellulose ethers. Both Menkart and Block are concerned with producing crosslinked cellulose ethers for use in aqueous solutions; thus, the skilled artisan could have substituted one known element for another, and could have predicted that the resulting product would be useful in aqueous solutions. Menkart also teaches that there is a recognized problem in the art (solubility of cellulose ethers) which could be solved by crosslinking the cellulose ethers. Block teaches a finite number of examples of crosslinking agents which can be used to prepare crosslinked cellulose ethers which are suitable for use in aqueous solutions. One of ordinary skill in the art could have pursued the potential solutions (crosslinking agents) taught by Block with a reasonable expectation of success. Further, although Menkart does not teach the steps of comminuting, milling, and drying, Menkart does teach a drying step, does teach pulverization of the product after drying and does teach a desirable particle size. It has been held that merely reversing the order of steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. Ex parte Rubin, 128 U.S.P.Q. 440 (P.O.B.A. 1959). Cohn v. Comr. Patents, 251 F. Supp. 437, 148 U.S.P.Q. 486 (D.C. 1966).

Response to Arguments

Applicant's arguments which are relevant to the new ground of rejection are addressed here.

Applicant argues that there is no motivation to incorporate the recited chemical compound into the method of Menkart because there would be no expectation of success. Block teaches crosslinking of cellulose ethers with glyoxylic acid, which provides an expectation of success.

Applicant argues that Menkart does not teach a method in which the cellulose ether is admixed but not dissolved in the reaction medium prior to reaction. Menkart teaches that the reaction should be carried out in a medium which is a non-solvent for the cellulose derivative itself [column 3, line 18], that the cellulose derivative should be suspended in the solvent [column 3, line 36], or that the cellulose derivative be only moistened with the solvent [line 53].

Applicant argues that Menkart is silent as to solvation delay. Menkart teaches products which dissolve in water "within a few minutes" [column 5, line 69]. Menkart also teaches that use of more crosslinking agent results in cross-linkages formed to such an extent that solubility is impaired [column 5, lines 3-8]. Thus, solvation delay is present in the teachings of Menkart and Menkart provides guidance as to the effect of crosslinking on solubility.

Applicant argues that Menkart does not teach the steps of comminuting, milling, and drying. Menkart does teach a drying step and does teach pulverization of the

product after drying. Further, Menkart teaches desirable particle size. It has been held that merely reversing the order of steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. Ex parte Rubin, 128 U.S.P.Q. 440 (P.O.B.A. 1959). Cohn v. Comr. Patents, 251 F. Supp. 437, 148 U.S.P.Q. 486 (D.C. 1966).

Applicant's arguments regarding the Herron reference are moot in view of the new ground of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/
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